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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,705	02/15/2005	David Varon	26421U	2837

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,705	VARON, DAVID	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-61* is/are pending in the application.

4a) Of the above claim(s) *40-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/22/05; 12/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Currently, claims 26 – 39 are pending. Cancellation of claims 1 – 25 and amendments to claims 27 – 39 is acknowledged. Further, claims 40 – 61 are acknowledged as withdrawn.

Withdrawn Rejections

Rejection of claims 30, 38 and 39 under 35 USC 112, second paragraph is withdrawn in light of Applicant's amendment and arguments filed on December 20, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26 – 33 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Berliner (US 2002/0001402).

The Berliner reference teaches a method for generating a profile of particulate components of a body fluid sample, wherein the profile can be used to detect or

diagnose a clinical condition, such as an inflammatory response in an individual (see paragraph [0082]). The method comprises mixing a fluid sample with a reagent that contains proteins or interacting molecules that can bind to molecules (analytes) found in the sample, creating a binding couple with the particulate components. The reagent is coated on a solid substrate, particularly a slide, wherein the reagent mixes with the fluid sample thus creating a thin layer of the particulates binding with the precoated reagent. The adherence of the particulates to the solid substrate is viewed and an optical image is obtained using an imaging device, such as a camera. The image is analyzed and the particulates are evaluated for their adherence to the substrate through their interaction with the coated reagents (i.e. proteins or antibodies) and further, the particulates are analyzed for additional parameters (see paragraphs [0029], [0091], [0096], [0098], [0104]-[0107], and [0138]).

With respect to Applicant's claim 27, Berliner teaches the analyte in the form of specific cell surface molecules, wherein more than one recognition site is available and the interacting molecule (capturing agent) precoated on the substrate is preferably in the form of an antibody, which comprises at least two capturing moieties. Therefore, the association between the surface molecules (analyte) and the capturing moiety of the antibody forms a binding couple, which adheres to the surface of the substrate (see paragraphs [0227]-[0230]).

With respect to Applicant's claim 28, the parameters evaluated for the adhered particulates include: particulates' count, aggregation (size), degree of aggregation (size

distribution), aggregate composition (shape distribution), concentration, shape, etc. (see paragraphs [0104] and [0105] in particular).

With respect to Applicant's claims 29 and 30, the image acquired of the adhered particulates is a magnified image, preferably obtained from a light microscope (see paragraph [0096]).

With respect to Applicant's claims 31 – 33, the analyte studied by Berliner is a particle in the form of a cell, which presents specific cell surface molecules, which are capable of interacting with the molecules (capturing agents) adhered to the surface of the substrate. The cell surface molecules thus contain more than one copy of an epitope or recognition site which can associate with the interacting molecules (capturing agent). The interacting molecules are preferably in the form of antibodies, which interact with an epitope(s) (recognition site) of the specific cell surface molecules (antigens) (see Example 7 and Table 3 on pg. 14 in particular).

With respect to Applicant's claim 39, Berliner teaches the particulates that adhere to the substrate through binding can be in the form of a thin layer or monolayer of cells (see paragraphs [0138], [0251] and Figures 17a, 17b and 22a in particular).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34 – 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berliner (US 2002/0001402) in view of Kelso (US 2003/0129296).

The Berliner reference, which has been discussed in the 102(e) rejection above, fails to teach that the reagent comprises microbeads having a sensing interface, wherein the sensing interface carries capturing moieties.

Kelso teaches film-immobilized capture particles wherein particles (microbeads) are coated with capture reagents (sensing interface), which are molecules attached to the surface of the particles that are capable of binding to the target molecule. The capture reagents include antibodies (monoclonal or polyclonal), receptors, proteins, nucleic acids, polymers, etc. (see paragraphs [0030]-[0032]). Kelso teaches the capture particles for forming a microarray wherein at least two unique capture particle species (capturing moieties) are attached to the particles' surface, which can represent the same capture particles species or different capture particle species (see claims 1,2 and 16 in particular). The use of the particles (microbeads) pre-coated with specific capture reagents to form the capture agents allows for many points of attachment for the target

molecules, which increases coupling efficiency and assay sensitivity (see paragraphs [0004], [0005] and [0055]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine with the method of Berliner the use of particles coated with the capture reagents (sensing interface) as taught by Kelso because Kelso teaches the benefit of using particles pre-coated with specific capture reagents to form the capture agents because they allow for many points of attachment for the target molecules, which increases coupling efficiency and assay sensitivity.

With respect to Applicant's claims 37 and 38, the particles taught by Kelso can have a variety of capture reagents attached to their surface, the capture reagents are any molecule that are capable of binding to the target molecule, which would therefore, represent an "affinity" particle (microbead). Further, the capture reagents can be in the form of proteins, particularly receptors useful for detecting immune responses or immune complexes, which therefore, represent immunoparticles (beads) (see paragraphs [0032] and [0069]).

Response to Arguments

Applicant's arguments filed December 20, 2005 have been fully considered but they are not persuasive. Applicant argues that the Berliner reference, used in the 102(e) rejection above, fails to teach "mixing" of a fluid sample with a reagent comprising a capturing reagent, such that particulates of a binding couple are formed in

the mixture prior to forming a thin layer on the substrate (see page 9). However, this argument is not found persuasive because Berliner does in fact teach mixing of the sample with a capture reagent in the form of proteins or interacting molecules that bind to molecules (analytes) found in the sample, thus creating a binding couple of particulate components resulting in a thin layer of particulates on the solid substrate (see Figures 17a and 17b; and Example 7 in particular). The mixing and creation of particulates taught by Berliner occurs on the solid substrate at primarily the same time, which is not excluded by the recited claims of the instant application, because the order in which the mixing of the sample, creation of the particulates, and forming of a thin layer on the solid substrate, as recited in the instant application, could occur at the same time.

Applicant also argues that the particulates of the binding couple are not formed in the Berliner reference because the capturing protein is "immobilized" on the substrate/slide (see page 9). However, this argument is irrelevant because the reagent recited in the instant application does not exclude the reagent from being coated or immobilized on the solid substrate. Thus, Berliner does teach the formation of particulates as the sample mixes with the coated capture reagent found on the solid substrate (see Figures 17a and 17b; and Example 7).

Finally, Applicant argues that Berliner does not teach the formation of a "thin layer," but requires that the layer formed on the glass slide be of "varying thickness" (see page 9-10). Again, this argument is not found to be persuasive because Berliner does teach an embodiment wherein a "thin layer" of particulates is formed on the solid

substrate. The embodiment disclosed in Example 7 and displayed in Figures 17a and 17b, allows for a thin layer of particulates to form on the solid substrate wherein sample cells adhere to the substrate through the mixing of the sample with the reagent coated onto the substrate, wherein the reagent is in the form of antibodies or molecules capable of interacting with the cell surface molecules. Therefore, an affinity slide is created on the solid substrate, which displays a thin layer of cells or particulates formed on the solid substrate/slide. The figures and paragraphs recited by the Applicant in the argument, particularly Figures 20a and 20b, as well as paragraphs [0077]-[0080], [0115], and [0235]-[0248], teach a separate embodiment wherein a layer of varying thickness of particulates can be formed on the solid substrate in order to perform volumetric analysis of the sample (see Example 8 of Berliner). Thus, Applicant's argument is found to be irrelevant because it is pertaining to only one embodiment of Berliner, and not to the embodiment wherein a thin layer of particulates is formed on the solid substrate.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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